

09/912,252

5

51876AUSM1

**REMARKS**

Applicant has amended Claims 28 and 30, cancelled Claim 41 and added new claim 42.

**Rejection under 35 U.S.C. §112, first paragraph**

The Examiner has rejected Claims 28-37 and 40-41, under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, stating that there is literally "no written support" for the concept of "simply inhibiting cell proliferation in a human target cell population".

Applicants have amended Claim 28 to indicate that the method does not "simply inhibit cell proliferation" but rather results in an "increased inhibition of cell proliferation" in a target cell population when that cell population are exposed to human type I IFN.

Written support for amended Claim 28 is present in the Specification on pg 6, line 20 to page 7, line 1, where the Applicants describe the use of the claimed method in treatment of diseases characterized by unwanted cell proliferation, as well as in Examples 2 and 3 (Figures 2 and 4), which demonstrate increased inhibition of cell proliferation in cells transfected with a functional INFACR2c gene as compared with untransfected cells.

Amended Claim 28 also indicates that the human IFNAR2c gene is introduced into the target cell population *in vitro*. Dependent claims 35, 37 and 40 describe different methods that are useful for the introduction of an exogenous gene, in this case, the human IFNAR2c gene, into human cells. Viral vectors have been used for successful delivery of genes into cells *in vitro* and examples of such transfection are present in the Specification (e.g. Examples 2 and 3).

New claim 42 has been added relating to the use of electroporation to introduce naked DNA or plasmid DNA into cells, a method which is well-known by those of skill in the art.

Applicants believe that with the amendments made to Claim 28 and the arguments presented above, presently pending claims 28-41 are enabled.

**Rejection under 35 U.S.C. §112, second paragraph**

The Examiner has rejected Claim 30 under 35 U.S.C. §112, second paragraph, for being indefinite, as the terms "type I c-IFN", "type I R-IFN" and "type I W-IFN" are not commonly found in the art. Claim 30 has been amended to correct what were errors unknowingly generated

51876AUSM1rccamd2

09/912,252

6

51876AUSM1

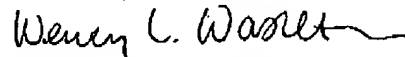
during transfer of the Amendment from one computer format to another. The amended Claim uses the terms  $\alpha$ ,  $\beta$  and  $\omega$ , commonly found in the art and in the Specification on page 3, lines 27-29.

Applicants believe that amended Claim 30 is not indefinite and request withdrawal of the rejection.

Conclusion:

Applicants believe that with the amendment of Claims 28 and 30 and the arguments presented above, the Claims are in condition for allowance.

Respectfully submitted,



Wendy L. Washtien, Ph.D.  
Agent for Applicant  
Reg. No. 36,301

Berlex Biosciences  
2600 Hilltop Drive  
Richmond, CA 94806  
Telephone: (510) 262-5411  
Fax: (510) 262-7095  
Date: July 25, 2005

51876AUSM1rceamd2